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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,972	01/06/2006	Hee-Jong Shin	Q92242	7325

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	**PAPER NUMBER**
4173	

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10/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,972	SHIN ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1 - 7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1 - 7 is/are rejected.

7)☒ Claim(s) 4 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 06 January 2006 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2 sheets.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1 – 7 are pending and are currently under examination.

Claim Objections

1. Claim 4 is objected to because of the following informalities: Claim 4 recites "a solid dispersion according to any one of claim 1 through 3 comprising additives". As no additives are mentioned in any of the referenced claims, it is assumed that the solid dispersion of claim 4 "further comprises" additives. This interpretation of the claim was used for the art rejections presented below. Appropriate correction is required.

Claim Rejections - 35 USC § 112 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 – 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 contains the phrase "higher than or equal to about 7." The phrase "higher than or equal to" can be expressed by the mathematical

symbol "≥" and indicates a range that can include 7 and any values higher than 7. The term "about" indicates a range centered on the recited value. In this case, a range of numbers both above and below 7. Therefore, what values are included in the range "higher than or equal to about 7" cannot be determined.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 3 – 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Hata et al. (US Patent 6,346,537 B1) as evidenced by Ueda et al. (Journal of Drug Targeting, 2003, 11(1), p 37 – 43).

Hata et al. discloses a pharmaceutical composition as a solid dispersion of the compound FK506 (col 1, ln 12 – 19). The generic name of FK506 is tacrolimus (col 1, ln 48). Recommended proportions of the medicinally active substances relative to the total compositions are 0.01% - 20%, preferably 0.1 – 10% (col 11, ln 11 – 13).

Example 3, (2) (col 12, ln 34 – 37) of Hata et al. recites a composition comprising 1% FK506, polyoxyethylene hydrogenated castor oil, hydroxypropylmethylcellulose and lactose. Polyoxyethylene hydrogenated castor oil is also known as HCO-40, HCO-60,

Cremophor RH40, Cremophor, RH60 etc. (col 9, ln 11 – 13). HCO-60 has a hydrophile lipophile balance (HLB) value of 14.0 (Udea et al., Table I, p 38).

Example 3, (21) (col 14, ln 13 – 19) of Hata et al. is a composition comprising 1% FK506, polyoxyethylene hydrogenated castor oil, polyvinylpyrrolidone, crospovidone, calcium stearate and corn starch. As disclosed in the specification of the instant application, starch is an excipient (p 5, ln 26), crospovidone is a disintegrator (p 5, ln 26 – p 6, ln 1) and calcium stearate is a lubricant (p 6, ln 2 – 3).

The compositions of Hata et al. are made by dissolving the medicinally active substance (e.g. FK506 or tacrolimus) and the surfactants in organic solvents such as ethanol. A carrier is added and after kneading, the organic solvent is removed and the residue dried and pulverized (col 10, ln 56 – 62). Excipients and disintegrators may be added to the kneading procedure where necessary (col 10, ln 62 – 65).

Thus, both Applicant and the prior art disclose a method of making a solid dispersion comprising tacrolimus and a solid surfactant with a HLB greater than or equal 7 with or without the addition of additives. Also disclosed by both Applicant and the prior art are compositions of tacrolimus and a solid surfactant with a HLB value greater than or equal to 7. Therefore, Hata et al. inherently meets the claim limitations of the instant application since they use the open language of comprising and the claims do not recite the absence of a solid carrier.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hata et al.

As discussed above, Hata et al. teaches compositions comprising tacrolimus and a solid surfactant with a HLB values greater than 7. The example compositions of Hata et al. do not use sodium lauryl sulfate, poloxamers and/or sucrose fatty acid esters.

Hata et al. does teach that sucrose fatty acid esters (col 9, ln 33 – 35), polyoxyethylene-polyoxyproplyene copolymer and block copolymer surfactants such as Poloxamer 188 and Poloxamer 225 (col 9, ln 36 – 40) and sulfuric acid alkyl esters such as sodium lauryl sulfate (col 9, ln 41) are surfactants that can be employed in the compositions (col 8, ln 53 – 60).

Therefore one of ordinary skill in the art at the time of the instant invention would have a had a reasonable expectation of success in substituting sodium lauryl sulfate or a poloxamer or sucrose fatty acid esters into the exemplified compositions of Hata et al. since Hata et al. teaches that each of these surfactants are all suitable for use in compositions comprising tacrolimus and a surfactant.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hata et al. as applied to claims 1 – 6 above in view of Patel et al. (US Patent 6,248,363 B1).

As discussed above, Hata et al. teaches compositions of tacrolimus and a surfactant with a HLB value of above 7 but does not teach making the composition using a spray drying process.

Patel et al. teaches pharmaceutical compositions for the delivery of drugs (col 1, ln 6 – 8). One formulation comprises tacrolimus (Example 20, col 60). One possible way to make the compositions taught by Patel et al. is spray drying (col 48, ln 15 – 35).

A person of ordinary skill in the art at the time of the instant invention would have a reasonable expectation of success in replacing one well known process of making a composition (drying and then pulverizing or milling the resultant material) with another well known process (spray drying), therefore making obvious claim 7 of the instant application.

Conclusion

Claims 1 – 7 are rejected. Claim 4 is objected to. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571) 270-3532. The examiner can normally be reached on M - F, 7:30 a.m. - 5 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718 or Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NMW

10/11/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER